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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,888

08/01/2003

Joerg Martin Bentzien

9/254

3053

28509

7590

11/17/2004

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,888	Applicant(s) BENTZIEN ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 21, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

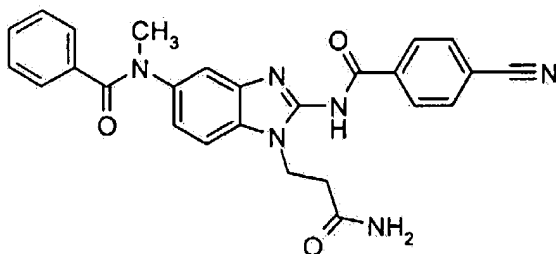
- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/03; 12/19/03; & 2/12/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I, and elected the species of the fourth compound (reproduced below) on page 35 of the instant specification, in the reply filed on October 21, 2004 is acknowledged.



The requirement is still deemed proper and is therefore made
FINAL.

Claims 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on October 21, 2004.

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Information Disclosure Statement

The Information Disclosure Statements filed on September 29, 2003, December 19, 2003 and February 12, 2004 have been considered by the Examiner.

Claim Objections

Claims 7 and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claims 1-6 are objected to because of the following informalities:

- a) in claim 1, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”;
- b) in claim 1, under the definition of R_5 , the phrase “each R_5 optionally” should be changed to “each R_5 is optionally”;

c) in claim 2, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”;

d) in claim 3, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”;

e) in claims 2 and 3, under the definition of R_5 , the phrase “ C_{1-5} alkyl, heteroaryl $C_{0.5}$ alkyl” should be changed to “ C_{1-5} alkyl and heteroaryl $C_{0.5}$ alkyl”;

f) in claims 2 and 3, under the definition of R_5 , the phrase “and heterocyclyl $C_{0.5}$ alkyl wherein” should be changed to “and heterocyclyl $C_{0.5}$ alkyl, wherein”;

g) in claim 4, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”;

h) in claim 4, under the definition of R_5 , a comma should be added before the phrase “each optionally substituted”;

i) in claim 5, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”;

j) in claim 5, under the definition of R_5 , a comma should be added before the phrase “each optionally substituted”; and

k) in claim 6, under the definition of R_2 , a comma should be added before the phrase “each R_2 is optionally substituted”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:


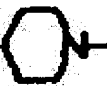


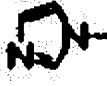
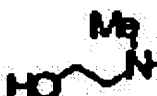
A person shall be entitled to a patent unless –

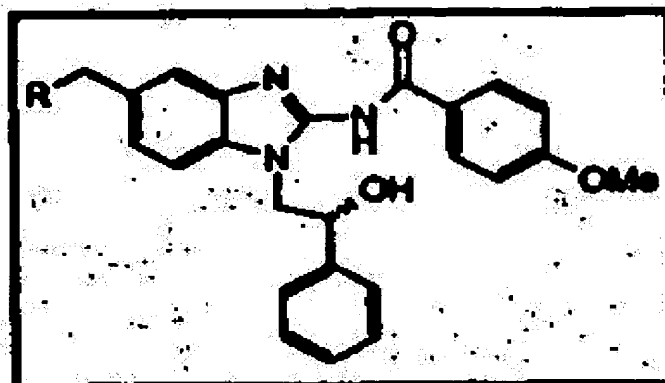
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Fang et al. {2-Aminobenzimidazoles as Neuropeptide Y Y5 Antagonists: Solution Phase Synthesis and Structure-Activity Relationships, ACS National Meeting, Chicago, IL, August 26, 2001, Abstract, MEDI 26}.

Fang et al. disclose, for example, compound 17^c, in the second table under the “Results” section, reproduced below, which is embraced by the instant claimed invention when instant R₁ is hydrogen, X_a is oxygen, R₂ is aryl substituted with R_a (e.g., 4-methoxyphenyl), R₃ is an unbranched alkyl substituted with one or more R_b (e.g., 2-hydroxy-2-phenylethyl), R_d is hydrogen, R₄ is -(CH₂)_t-NR₇R₅, t is 1, R₇ and R₅ together with the nitrogen atom to which they are attached form a 4-7-membered monocyclic nonaromatic ring (e.g., a pyrrolidinyl ring). Therefore, the instant claimed invention is anticipated by Fang et al.

compound number	R	IC ₅₀ (nM)	Rel 30 (PCT)	MOCK (OP ratio)	Eq 8d (SIF, mg/ml)
15 ^B	-NMe ₂	83	10	0.69	1.08
16 ^B	-NE ₂	128	43	0.56	1.24
17 ^C		68	0	0.47	0.21
18 ^C		47	27	0.56	0.78
19 ^A	MeN 	24	16	0.44	0.81
20 ^C		6	83	0.50	0.014
21 ^C		32	8	0.20	0.002
22 ^C		49	11	0.12	0.96



A B C route used to prepare the compound

- ¹ OP = Cell Permeability (PAPP, nm/sec)
- OP ratio = OP(compound)/OP(propensol)
- ² SIF (simulated intestinal fluid, pH = 6.6)
- ³ mesylate salt

Frenkel et al. disclose, for example, Compound 30 in Figure 1e which is embraced by the instant claimed invention when instant R₁ is hydrogen, X_a is oxygen, R₂ is aryl substituted with R_a (e.g., 3-

nitrophenyl), R_3 is an unbranched alkyl substituted with R_b (e.g., 3-hydroxypropyl), R_d is hydrogen, R_4 is $-(CH_2)_t-NR_7R_5$, t is 1, R_7 is alkyl (e.g., methyl), and R_5 is alkyl (e.g., methyl). Therefore, the instant claimed invention is anticipated by Frenkel et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frenkel et al. {U.S. Pub. No. 2003/0144286}, Craig et al. {U.S. Pat. 3,336,191}, Craig et al. {U.S. Pat. 3,401,171}, Chow et al. {U.S. Pat. 3,401,173}, Grier {U.S. Pat. 4,011,236} and Smith Kline & French Laboratories {GB 1,122,957}, each taken alone or in combination with each other when similar utilities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim benzimidazole compounds. **Frenkel et al.** (Formula I on pages 6-7; Formula IIa on pages 8-9; Formula IV on page 10; Formula VII on page 11; the compositions on page 13, paragraphs [0140] through [0143]; the different forms of the compounds on page 5, paragraphs [0053] through [0057]; and especially Compound 30 in Figure 1e), **Craig et al. '191** (column 1, lines 15-48; column 5, lines 18-73; and especially the compounds in column 2, lines 20 and 47, Example 18 in column 9 and Example 30 in column 13), **Craig et al. '171** (column 1, lines 32-69; column 5, lines 28-41; and especially the compounds in column 2, lines 39 and 41, and Example 22 in column 9), **Chow et al.** (column 1, lines 24-54, column 2, lines 70-72; column 3, lines 1-5; and especially the compound in column 4, line 60 and Example 6 in column 5), **Grier** (column 1, lines 40-68; column 2, lines 1-5, 17-19 and 28-39; and especially the compound in column 2, lines 44-45 and the compound in column 3, line 37) and **Smith Kline & French Laboratories** (page 1, columns 1 and 2; page 3, column 2, lines 103-110;

page 4, column 1, lines 1-11; and especially and Example 22 on page 8) each teach benzimidazole compounds that are either structurally the same as (see above 102 rejections) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., anti-inflammatory).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed

compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, inflammatory disorders. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

The elected the species of the fourth compound on page 35 of the instant specification is not allowable. See Frenkel et al. {U.S. Pub. No. 2003/0144286}.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

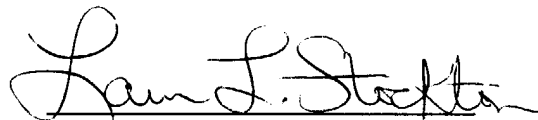
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

November 15, 2004